

1. (Currently Amended) A method for regulating expression of a *tet* operator-linked gene in a cell of a subject, comprising:
 - directly introducing into the cell a first nucleic acid molecule comprising the *tet* operator-linked gene;
 - directly introducing into the cell a second nucleic acid molecule encoding a tetracycline-controllable transactivator (tTA), the tTA comprising a Tet repressor operably linked to a polypeptide which directly or indirectly activates transcription in eucaryotic cells;
 - wherein the first and second nucleic acid molecules are not covalently linked to each other; and
 - modulating the concentration of a tetracycline, or analogue thereof, in the subject.
2. ~~18~~ (Previously presented) A method for regulating expression of a *tet* operator-linked gene in a cell of a subject, comprising:
 - introducing into the cell a single nucleic acid molecule comprising the *tet* operator-linked gene and also encoding a tetracycline-controllable transactivator (tTA), the tTA comprising a Tet repressor operably linked to a polypeptide which directly or indirectly activates transcription in eucaryotic cells; and
 - modulating the concentration of a tetracycline, or analogue thereof, in the subject.
3. ~~2~~ (Previously presented) The method of claim 1 or ~~18~~², wherein the Tet repressor of the tTA is a Tn10-derived Tet repressor.
4. ~~3~~ (Previously presented) The method of claim 1 or ~~18~~², wherein the polypeptide of the tTA which directly or indirectly activates transcription in eucaryotic cells is from herpes simplex virus virion protein 16.
5. ~~4~~ (Previously presented) The method of claim ~~18~~², wherein the nucleic acid molecule encoding the tTA is integrated randomly in a chromosome of the cell.
6. ~~5~~ (Previously presented) The method of claim ~~18~~², wherein the nucleic acid molecule encoding the tTA is integrated at a predetermined location within a chromosome of the cell.

7 ~~6~~ (Previously presented) The method of claim 1 or ~~18~~², wherein the nucleic acid molecule encoding the tTA is introduced into the cell *ex vivo*, the method further comprising administering the cell to the subject.

Claims 7-8. (Canceled)

8 ~~9~~ (Previously presented) The method of claim 1 or ~~18~~², wherein the tetracycline analogue is anhydrotetracycline, doxycycline or cyanotetracycline.

9 ~~10~~ (Previously presented) A method for regulating expression of a *tet* operator-linked gene in a cell of a subject, comprising:
obtaining the cell from the subject;
introducing into the cell a first nucleic acid molecule comprising the *tet* operator-linked gene;
introducing into the cell a second nucleic acid molecule encoding a tetracycline-controllable transactivator (tTA), the tTA comprising a Tet repressor operably linked to a polypeptide which directly or indirectly activates transcription in eucaryotic cells, to form a modified cell;
wherein the first and second nucleic acid molecules are not covalently linked to each other;
administering the modified cell to the subject; and
modulating the concentration of a tetracycline, or analogue thereof, in the subject.

10 ~~11~~ ~~19~~ (Previously presented) A method for regulating expression of a *tet* operator-linked gene in a cell of a subject, comprising:
obtaining the cell from the subject;
introducing into the cell a single nucleic acid molecule comprising the *tet* operator-linked gene and also encoding a tetracycline-controllable transactivator (tTA), the tTA comprising a Tet repressor operably linked to a polypeptide which directly or indirectly activates transcription in eucaryotic cells, to form a modified cell;
administering the modified cell to the subject; and
modulating the concentration of a tetracycline, or analogue thereof, in the subject.

11 ~~12~~ ~~11~~ (Previously presented) The method of claim ~~10~~⁹ or ~~19~~¹⁰, wherein the Tet repressor of the tTA is a Tn10-derived Tet repressor.

12¹²³ 12. (Previously presented) The method of claim ^{9, 10}~~10~~ or 19, wherein the polypeptide of the tTA which directly or indirectly activates transcription in eucaryotic cells is from herpes simplex virus virion protein 16.

13¹⁴ 13. (Previously presented) The method of claim ^{9 10}~~10~~ or 19, wherein the nucleic acid molecule encoding the tTA is integrated randomly in a chromosome of the cell.

14¹⁵ 14. (Previously presented) The method of claim ^{9 10}~~10~~ or ~~19~~, wherein the nucleic acid molecule encoding the tTA is integrated by homologous recombination at a predetermined location within a chromosome of the cell.

Claims 15-16. (Canceled)

15¹⁶ 15. (Previously presented) The method of claim ^{9 10}~~10~~ or ~~19~~, wherein the tetracycline analogue is anhydrotetracycline, doxycycline or cyanotetracycline.